

**Notice of Allowability**

Application No.

10/071,214

Examiner

Valarie Bertoglio

Applicant(s)

HANSSON ET AL.

Art Unit

1632

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 03/15/2005.
2. ☒ The allowed claim(s) is/are 1,2,11-13,15,29,30,32-35,44 50 and 70-72.
3. ☒ The drawings filed on 02/11/2002 are accepted by the Examiner.
4. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some\* c) ☐ None of the:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |   |   |
|---|---|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892)  | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)           |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                | 6. <input type="checkbox"/> Interview Summary (PTO-413),<br>Paper No./Mail Date _____ |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),<br>Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment                   |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material          | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance  |
|   | 9. <input type="checkbox"/> Other _____   |

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### EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

#### *Rejoinder of Claims*

Claims 1,2,11-13 and 15 are directed to an allowable product. Pursuant to the procedures set forth in the Official Gazette notice dated March 26, 1996 (1184 O.G. 86), claims 47-51, directed to the process of making or using the patentable product, previously withdrawn from consideration as a result of a restriction requirement, are now subject to being rejoined. Claims 47-51 are hereby rejoined and fully examined for patentability under 37 CFR 1.104. Claims 44 and 50 are amended below such that they are commensurate in scope with the allowable product. Remaining rejoined method claims are not commensurate in scope with the product and are cancelled as set forth below.

Authorization for this examiner's amendment was given in a telephone interview with Iver Cooper on April 12, 2005.

The application has been amended as follows:

In the claims,

Claim 1. A transgenic mouse, having integrated within its genome a nucleotide sequence (SCCE-construct) comprising a heterologous nucleotide sequence coding for a human stratum corneum chymotryptic enzyme (SCCE), operably linked to a SV40 early promoter that drives expression

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of said heterologous nucleotide sequence in skin, wherein the mouse exhibits epidermal hyperplasia and hyperkeratosis and a mild cellular inflammatory reaction of the skin.

Claim 44. A method of identifying a compound or composition effective for the prevention or treatment of epidermal hyperkeratosis, acanthosis, epidermal inflammation, dermal inflammation and pruritus, the method comprising

- (a) administering a compound or composition to a transgenic mouse according to claim 1,
- (b) evaluating the appearance of the skin and/or the behavior of a mouse treated according to step (a), and
- (c) comparing the appearance of the skin and/or the behavior of a treated mouse with an untreated control mammal,
- (d) identifying the compound or composition as being effective for the prevention or treatment of epidermal hyperkeratosis, acanthosis, epidermal inflammation, dermal inflammation and pruritus.

Claims 47-49. Cancelled

Claim 50. A method according to claim 44 of identifying a compound or composition effective for the prevention or treatment of epidermal hyperkeratosis.

Claim 51. Cancelled

***Reasons for Allowance***

The following is an examiner's statement of reasons for allowance: Applicant has overcome the enablement issues by amending claim 29 in the After Final amendment dated 03/15/2004, limiting the cell type used to make the claimed mouse. Applicant has also amended the claims to address and overcome the rejection under 35 USC 112, 2<sup>nd</sup> paragraph.

Previously withdrawn method claims have been amended to be consistent in scope with the allowed product. The method claims are free of the art of record because they use the product of claim 1, which was originally elected and has been the subject of examination. The allowed method claims are drawn to an enabled method of use of the transgenic mouse wherein the mouse is used to screen for potential therapeutics.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

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***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Valarie Bertoglio whose telephone number is (571) 272-0725.

The examiner can normally be reached on Mon-Thurs 5:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Valarie Bertoglio  
Examiner  
Art Unit 1632

JOSEPH WOITACH, PH.D.  
PRIMARY EXAMINER



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